



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**[CMS-3428-FN]**

### **Medicare and Medicaid Programs: Application from the National Dialysis Accreditation Commission (NDAC) for Continued Approval of its End-Stage Renal Disease (ESRD) Facility Accreditation Program**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces our decision to approve the National Dialysis Accreditation Commission (NDAC) for continued recognition as a national accrediting organization for End-Stage Renal Disease (ESRD) facilities that wish to participate in the Medicare or Medicaid programs.

**DATES:** This notice is applicable January 4, 2023 through January 4, 2029.

**FOR FURTHER INFORMATION CONTACT:** Caecilia Blondiaux, (410) 786-2190.

### **SUPPLEMENTARY INFORMATION:**

#### **I. Background**

Under the Medicare program, eligible beneficiaries may receive covered services from a hospital, provided certain requirements are met. Section 1881(b) of the Social Security Act (the Act) establishes statutory authority for the Secretary of the Department of Health and Human Services (Secretary) to set criteria for facilities seeking designation as a dialysis facility (also known as an “end-stage renal disease (ESRD) facility”). Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 494 specify the minimum conditions for coverage that an ESRD facility must meet to participate in the Medicare program.

Generally, to enter into an agreement, an ESRD facility must first be certified by a state survey agency (SA) as complying with the conditions or requirements set forth in part 494 of our regulations. Thereafter, the ESRD facility is subject to regular surveys by a SA to determine whether it continues to meet these requirements.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS)-approved national accrediting organization (AO) that all applicable Medicare requirements are met or exceeded, we will deem those provider entities as having met such requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by CMS as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare requirements. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare requirements. Our regulations concerning the approval of AOs are set forth at §§ 488.4, 488.5 and 488.5(e)(2)(i). The regulations at § 488.5(e)(2)(i) require AOs to reapply for continued approval of its accreditation program every 6 years or sooner, as determined by CMS.

The National Dialysis Accreditation Commission's (NDAC's) current term of approval for their ESRD facility accreditation program expires January 4, 2023.

## **II. Application Approval Process**

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a

notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

### **III. Provisions of the Proposed Notice**

On May 23 2022, we published a proposed notice in the **Federal Register** (87 FR 31241), announcing NDAC's request for continued approval of its Medicare ESRD facilities accreditation program. In that proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5 and § 488.8(h), we conducted a review of NDAC's Medicare ESRD facilities accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An administrative review of NDAC's: (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its ESRD facility surveyors; (4) ability to investigate and respond appropriately to complaints against accredited ESRD facilities; and (5) survey review and decision-making process for accreditation.

- A review of NDAC's survey processes to confirm that a provider or supplier, under NDAC's ESRD facilities deeming accreditation program, meets or exceeds the Medicare program requirements.

- A documentation review of NDAC's survey process to do the following:
  - ++ Determine the composition of the survey team, surveyor qualifications, and NDAC's ability to provide continuing surveyor training.
  - ++ Compare NDAC's processes to those we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against NDAC accredited ESRD facilities.

++ Evaluate NDAC's procedures for monitoring accredited ESRD facilities it has found to be out of compliance with its program requirements.

++ Assess NDAC's ability to report deficiencies to the surveyed ESRD facilities and respond to the ESRD facilities plan of correction in a timely manner.

++ Determine the adequacy of NDAC's staff and other resources.

++ Confirm NDAC's ability to provide adequate funding for performing required surveys.

++ Confirm NDAC's policies with respect to surveys being unannounced.

++ Confirm NDAC's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ Obtain NDAC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

#### **IV. Analysis of and Responses to Public Comments on the Proposed Notice**

In accordance with section 1865(a)(3)(A) of the Act, the May 23, 2022 proposed notice also solicited public comments regarding whether NDAC's requirements met or exceeded the Medicare conditions for coverage for ESRD facilities. We received no comments.

#### **V. Provisions of the Final Notice**

##### **A. Differences Between NDAC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements**

We compared NDAC's ESRD facilities accreditation requirements and survey process with the Medicare conditions for coverage of parts 494, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of NDAC's renewal application, which were conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, NDAC has revised its standards and certification processes in

order to meet our requirements at:

- Section 494.30(a)(2), to specify the requirement to implement the guidelines as outlined in the Medicare regulations for the prevention of IV catheter-related infections.
- Section 494.60(c)(2)(i), to include reference to the 2008 ASHRAE 170 ventilation design parameters or a reference to these design parameters for ESRD facilities that are required to comply with the 2012 NFPA 99, as it relates to providing comfortable temperature within the ESRD facility.
- Section 494.60(e), to provide specific language which requires dialysis facilities that do not have one or more exits to grade level from the patient treatment level to meet the 2012 Health Care Facilities Code (NFPA 99), regardless of the number of patients served.
- Section 494.62(c)(1)(iv), to incorporate other dialysis facilities' contact information in the ESRD facility's emergency preparedness program as part of its communication plans.
- Section 494.70(a)(17), to specify that patients may file internal or external grievances, personally, anonymously or through a representative of the patient's choosing.

In addition to the standards review, CMS reviewed NDAC's comparable survey processes, which were conducted as described in section III. of this final notice, and yielded the following areas where, as of the date of this notice, NDAC has completed revising its survey processes in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

- Developing a process on how NDAC will obtain the Dialysis Facility Reports (DFRs) from its already-accredited facilities in accordance with survey comparability at § 488.5(a)(4)(ii).
- Revising NDAC's Life Safety Code Surveyor Responsibilities section to include survey responsibilities and licensure requirements to ensure the 2012 editions of the Life Safety Code (NFPA 101) and Health Care Facilities Code (NFPA 99) are met.
- Updating NDAC's Surveyor Field Manual to include surveyor process and worksheets for Life Safety Code and Health Care Facilities Code surveyors and revise other associated

documents as necessary.

- Revising NDAC's complaint policy to include prioritization classifications for complaints and timeframes to investigate based on the priority level in accordance with § 488.5(a)(12).
- Revising NDAC's survey processes for Emergency Preparedness to align with the CMS requirements. Specifically, to ensure surveyors review ESRD facility plans to include primary and alternate means for communicating as required by § 494.62(c)(3) and testing guidance in accordance with § 494.62(d)(2), including conducting after-action reviews after an actual emergency event.
- Clarifying that NDAC's policy for immediate jeopardy includes: (1) a process for providing the template to the dialysis facility; and (2) documentation of this information on the statement of deficiencies, in accordance with § 488.5(a)(4)(ii) and the State Operations Manual (SOM), Appendix Q Section VI. Calling Immediate Jeopardy.
- Providing additional education to NDAC surveyors on interviewing patients and staff using open-ended questioning, in accordance with SOM Chapter 2, Section 2714.
- Providing additional education and training to NDAC surveyors on emergency preparedness interviews of patients, staff and facility leadership to ensure the facility can demonstrate knowledge of the emergency preparedness program, including its policies and procedures, in accordance with the survey procedures in SOM Appendix Z.

#### B. Term of Approval

Based on our review and observations described in section III. and section V. of this final notice, we approve NDAC as a national accreditation organization for ESRD facilities that request participation in the Medicare program. The decision announced in this final notice is effective January 4, 2023 through January 4, 2029 (6 years). In accordance with § 488.5(e)(2)(i) the term of the approval will not exceed 6 years.

## **VI. Collection of Information and Regulatory Impact Statement**

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: September 28, 2022.

**Lynette Wilson,**

*Federal Register Liaison,*

*Centers for Medicare & Medicaid Services.*

[FR Doc. 2022-21415 Filed: 10/3/2022 8:45 am; Publication Date: 10/4/2022]